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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,450	07/09/2001	Luciano Pedrini	P66652US0	4235

7590 12/29/2003
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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,450

Applicant(s)

PEDRINI ET AL.

Examiner

John Kim

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 14, 16, 17 and 20-25 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/03 has been entered.

2. Claims 14, 17 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 in view of "Hemodialysis Machines and Monitors" by Polaschegg et al. in Replacement of Renal Function by Dialysis edited by C. Jacobs et al, pages 334-373 (hereinafter referred to as Polaschegg et al). WO 98/50091 teaches method and device for controlling a blood purifying device including hemofilter and hemodialyzer wherein a control unit (9-14) takes signals from weighing means (5, 6, 7) for measuring substitution product from reservoirs (15, 16) and ultrafiltrate (17) and adjusts the instantaneous flow rates of blood, ultrafiltrate and the substitution products by monitoring substitution pumps upstream and/or downstream of the blood purifying device (see abstract; figure 1). Operational parameter is one or more of blood flow rate, ultrafiltration rate, weight of ultrafiltrate. Controlling ultrafiltrate amount is closely correlated to the adjustment of substitution fluid input. Claims 14, 17 and 20-24 essentially differ from the method and apparatus of WO 98/50091 in reciting the operational and/or blood parameters are TMP, blood density and/or HKT and associated sensors for measuring the claimed parameters. Polaschegg et al teach that the ultrafiltration rate is controlled by the transmembrane pressure which is measured by pressure sensors in extracorporeal circuit and/or dialysis circuit (see figure 20; pages 348-349). Polaschegg et al further teach that ultrafiltration rate can be controlled by monitoring HKT and blood density (see figures 29-32; pages 360-362).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method and apparatus of WO 98/50091 to include known sensors for measuring TMP, HKT and/or blood density to improve the control of ultrafiltration and in turn adjustment of substitution fluid input in the method and apparatus of WO 98/50091.

3. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 in view of Polaschegg et al as applied to claim 14 above, and further in view of Pedrini et al, Abstract at EDTA/ERA Congress in Madrid (1999)(hereinafter referred to as Pedrini et al). Claim 16 essentially differs from the method of WO 98/50091 in view of Polaschegg et al in reciting that the infusion rate of the substitution solution supplied upstream of the hemodialyzer and/or hemofilter is preferably increased relative to the infusion rate supplied downstream of the hemodialyzer and/or hemofilter with increasing TMP, increasing blood density and/or increasing HKT. Pedrini et al teach that hemodiafiltration (HDF) with simultaneous pre- and post dilution avoids the risk due to overly high ultrafiltration rate and TMP without affecting solute removal as in pre-HDF and also allows higher ultrafiltration rate and is further ameliorable by optimizing the ratio of pre/post infusion to get higher FF and could be more efficient and safe mode in routine HDF. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the pre/post infusion rates of substitution solution to obtain higher ultrafiltration rate and TMP in more efficient and safe mode in routine HDF as suggested by Pedrini et al.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/50091 in view of Polaschegg et al as applied to claim 20 above, and further in view of German Patent No. 4240681 (hereinafter referred to as Polaschegg). Claim 25 essentially differs from the apparatus

of WO 98/50091 in view of Polaschegg et al in reciting that the means for controlling the infusion rates are valves in the supply lines. Polaschegg teaches a hemodiafiltration apparatus in which pre and post substitution fluid flow is controlled by valves (48, 104) directed by a control unit (58) (see figure 2). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of WO 98/50091 in view of Polaschegg et al by incorporating known control scheme with valves in the supply line of substitution fluid to control the infusion rates of the substitution fluid as suggested by Polaschegg.

5. Claims 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claims 26-27 are allowed.
7. Applicant's arguments with respect to claims 14 and 16-27 have been considered but are moot in view of the new ground(s) of rejection.
8. Formal drawing is required since allowable subject matter has been indicated. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

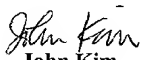
Application/Control Number: 09/900,450

Page 4

Art Unit: 1723

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
December 19, 2003